

### **REMARKS/ARGUMENTS**

Applicants have resubmitted the entire response previously filed on February 27, 2004, because several sections of the response were corrected in order to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003.

Each section of the Amendment now starts on separate sheet. Further, because the abstract has been substantially rewritten, a new abstract is submitted and an instruction for cancellation of the previous abstract has been provided. Finally, several formal amendments, not submitted with the previously filed response, have been made to the specification. Specifically, Applicants have deleted all references to embedded hyperlinks. In addition, the ATCC address on page 376, line 34, has been amended. (Applicants respectfully submit that all references to page and line numbers made throughout this response will be based on the parent Application No. 09/918,585, filed 7/30/2001, that was photocopied from the PTO files by the Applicants). Further, in compliance with the requirements necessary when deposits are made under the provisions of the Budapest Treaty, the paragraph beginning on page 378, line 33, has been amended to include language that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on this application. The PTO is kindly requested to enter these amendments.

Prior to the present amendment, Claims 58-63 were pending in this application and were rejected on various grounds. Claim 63 has been canceled and Claim 58 has been amended. The amendments to the specification concern the correction of a typographical error that was pointed out by the Examiner in related application Serial No. 09/978,802. The amendments are of formal nature and do not introduce new matter.

### **Priority**

The Examiner accorded the effective filing date of April 1, 1998 to the claims pending in this application, but held that the claimed invention lacked patentable utility. Applicants refer to parallel application Serial No. 09/978,802, claiming PRO701 polypeptides to which the present antibodies bind. In an Office Action mailed on January 5, 2004 in connection with that application, the Examiner accorded the effective filing date of February 18, 2000 to the claimed

polypeptides, and acknowledged that the data demonstrating the ability of the polypeptides to inhibit proliferation of stimulated T-lymphocytes in a mixed lymphocyte reaction, or to inhibit the survival of neural cells in cell culture, first disclosed in US application Serial No. 09/918,585 (07/30,2001) and PCT/US00/04341 (02/18/2000) established patentable utility. Applicants submit that the present application should be accorded the effective filing date of February 18, 2000 for the same reasons.

**Claim rejections - 35 USC § 101**

Claimed 58-63 have been rejected for alleged lack of a specific and substantial asserted utility or a well established utility for the invention claimed.

Applicants, again, refer to application Serial No. 09/978,802, where the Examiner acknowledged that the claimed polypeptides complied with the utility requirement set forth in 35 U.S.C. § 101, as a result of their demonstrated ability to inhibit proliferation of stimulated T-lymphocytes in a mixed lymphocyte reaction, or to inhibit the survival of neural cells in cell culture. Agonist antibodies specifically binding to a PRO701 polypeptide of SEQ ID NO: 375 have the same utility. Antagonist antibodies on the other hand are useful in blocking the activity of PRO701 polypeptides and are, therefore, useful, for example, in situations where nerve cell proliferation is required or beneficial, such as neurodegenerative diseases. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

**Claim Rejections - 35 USC § 112**

(1) Claims 58 and 63 were rejected under 35 U.S.C. § 112, first paragraph for alleged lack of written description for antibodies that specifically binds to a polypeptide of SEQ ID NO:375. Although original claim 58 did not include this recitation, it has now been so amended. Claim 63 has been canceled. Applicants respectfully traverse the rejection of claim 58 on this ground.

The terms “specific binding” and “specifically binds” are well known terms of art in antibody technology. One skilled in the art understands that specific binding means that an antibody binds to a unique epitope within a target sequence. The Written Description Guidelines clearly acknowledge that considering the routine and art-recognized methods of making

antibodies, the well defined characteristics of the five classes of antibodies, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, the disclosure of an antigen implicitly discloses an antibody which binds to that antigen. This general determination is equally true to antibodies which "specifically bind" to a target antigen, since such antibodies can be identified by routine screening in routine competitive binding assays. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

Applicants note that a quick search of the USPTO database identified 282 issued patents, which claim antibodies specifically binding to a specific polypeptide, which supports Applicants' position that established case law and the Patent Office's examination practice clearly acknowledges that antibodies specifically binding to a novel and unobvious polypeptide meet the written description requirement of the patent statute.

(2) Claims 68 and 73 were rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the enablement requirement. This rejection, again, is based on the recitation of the phrase "specifically binds to" in the claims. The Examiner asserts that antibodies with such specific binding properties are not enabled, since "specific binding to polypeptides is relatively unpredictable."

Applicants disagree, and vigorously traverse the rejection. The specification contains extensive teaching about the production of antibodies, including humanized antibodies, antibody fragments, etc. by various techniques. Antibodies which bind to a particular target with high specificity and do not significantly bind other structurally related molecules can be performed by routine competitive binding assays, without undue experimentation. Therefore, the present rejection is believed to be misplaced, and should be withdrawn.

#### **Claim Rejections - 35 USC § 102**

Claims 58-63 have been rejected under 35 USC 102(b) as being anticipated by Ichtchenko et al. teaching a neuroligin polypeptide, where residues 546-505 are identical with residues 510-559 of SEQ ID NO:375.

The rejection is respectfully traversed.

Since the claims recited antibodies that bind specifically to a polypeptide of SEQ ID NO:375, i.e., binds to a unique epitope within such polypeptide, they are not anticipated by Ichtchenko et al. Accordingly, the Examiner is requested to reconsider and withdraw the present rejection.


### **CONCLUSION**

In conclusion, all claims pending in this application are believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including fees for extension of time, or credit overpayment to Deposit Account No. **08-1641** (Attorney Docket No. **39780-630 P1C21**). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: April 1, 2004

By   
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